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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/596,815	06/26/2006	Alan G. Saltzman	USAV2003-0020 US PCT	1806

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EXAMINER	
ARCHIE, NINA	

ART UNIT	PAPER NUMBER
1645	

NOTIFICATION DATE	DELIVERY MODE
11/26/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/596,815	SALTZMAN ET AL.	
	Examiner	Art Unit	
	Nina A. Archie	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 June 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10* is/are pending in the application.

4a) Of the above claim(s) *7 and 8* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6 and 9-10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions, which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

1. Group I: claims 1-6 and 9-10 drawn to a method of identifying a compound capable of modulating the activity of Cathepsin Z in a cell.
2. Group II: claims 7-8 drawn to a compound capable of modulating the activity of Cathepsin Z identified and a pharmaceutical.

The inventions listed as Groups I-II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The technical feature of Group I is a method of identifying a compound capable of modulating the activity of Cathepsin Z in a cell. The technical feature of Group 1 is anticipated by Wisotzkey et al US Application NO. 20030159168 A1 Date August 21, 2003. Wisotzkey et al. teaches a method of identifying a compound capable of modulating the activity of Cathepsin Z in a cell (see abstract, [0020], [0024]). The special technical feature of Group II is a compound capable of modulating the activity of Cathepsin Z identified and a pharmaceutical. Group II lacks unity with Group I because they do not have the same technical feature.

During a telephone conversation with Ms. Karen Krupen on October 16, 2007 a provisional election was made without traverse to prosecute the invention of Group 1, claims 1-6 and 9-10. Affirmation of this election must be made by applicant in replying to this Office action. Group 2 (claims 7-8) are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one

or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Priority

3. Applicant's claim for domestic priority under 35 U.S.C. 119(e) is acknowledged.

Drawings

4. The drawings in this application have been accepted. No further action by Applicant is required.

Claim Rejections - 35 USC § 102 and 103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 1-2, 5, and 9-10 are rejected under 35 U.S.C. 102(a) as being anticipated by Wisotzkey et al US Application NO. 20030159168 A1 August 21, 2003.

Claims 1-2, 5, and 9-10 are drawn to a method of identifying a compound capable of modulating the activity of Cathepsin Z in a cell, comprising the steps of: (a) measuring said cell's base level of Cathepsin Z activity in the absence of a candidate compound; (b) introducing said candidate compound; and (c) measuring said cell's level of Cathepsin Z activity in the presence of said candidate compound.

Wisotzkey et al teach a method of identifying a compound capable of modulating the activity of Cathepsin Z in a cell, comprising the steps of: (a) measuring said cell's base level of Cathepsin Z activity in the absence of a candidate compound; (b) introducing said candidate compound; and (c) measuring said cell's level of Cathepsin Z activity in the presence of said candidate compound (abstract, [0020], [0024]), wherein said cell's level of Cathepsin Z activity is measured by measuring antigen presentation (i.e. macrophages see example 19 and example 20). Therefore Wisotzkey et al anticpate a method wherein cell is an antigen-presenting cell. Wisotzkey et al teach a method for treating an autoimmune disease comprising the step of administering the pharmaceutical of a compound capable of modulating the activity of Cathepsin Z, wherein said autoimmune disease is rheumatoid arthritis (see [0015],

[0087], [0089], [0172].

6. Claims 1-2, 5-6, and 9 are rejected under 35 U.S.C. 102(a) as being anticipated by Li et al WO 2003/079982.

Claims 1-2, 5, and 9 are drawn to a method of identifying a compound capable of modulating the activity of Cathepsin Z in a cell, comprising the steps of: (a) measuring said cell's base level of Cathepsin Z activity in the absence of a candidate compound; (b) introducing said candidate compound; and (c) measuring said cell's level of Cathepsin Z activity in the presence of said candidate compound.

Li et al teach a method of identifying a compound capable of modulating the activity of Cathepsin Z in a cell, comprising the steps of: (a) measuring said cell's base level of Cathepsin Z activity in the absence of a candidate compound; (b) introducing said candidate compound; and (c) measuring said cell's level of Cathepsin Z activity in the presence of said candidate compound (abstract), wherein said cell's level of Cathepsin Z activity is measured by measuring antigen presentation (see claims), wherein cell is an antigen-presenting cell. Li et al teach a method for treating an autoimmune disease (cancer) comprising the step of administering the pharmaceutical of a compound capable of modulating the activity of Cathepsin Z, (see abstract, pgs. 5-7).

7. Claims 1-6 and 9-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wisotzkey et al US Application NO. 20030159168 A1 August 21, 2003 in view of Copland et al 2003 (February 14, 2003), Vol. 21 pgs. 883-890.

Claims 1-2, 5, and 9 are drawn to a method of identifying a compound capable of modulating the activity of Cathepsin Z in a cell, comprising the steps of: (a) measuring said cell's base level of Cathepsin Z activity in the absence of a candidate compound; (b) introducing said candidate compound; and (c) measuring said cell's level of Cathepsin Z activity in the presence of said candidate compound.

Wisotzkey et al is relied upon as set forth supra. However Wisotzkey et al does not teach a method wherein said cell's level of antigen presentation is measured by measuring autologous T-cell response to tetanus toxin, wherein said cell's level of antigen presentation is measured by measuring said cell's capacity to present quenched FITC-ovalbumin, wherein said antigen-presenting cell is selected from the group consisting of dendritic cell precursor, immature dendritic cell, and mature dendritic cell.

Copland et al that dendritic cells are highly potent profession antigen-presenting cells essential for initiation of an immune response. Copland et al teach that immature human dendritic cells were generated from peripheral blood monocytes cultured with GM-CSF and IL-4 and that the uptake of antigen by dendritic cells and the degree of expression of the cell surface markers MHC class II, CD80, CD86 and the DC maturation marker CD83, were investigated by incubation solution containing FITC-conjugated antigen. Copland et al teach that exposure to FITC–ovalbumin resulted in enhanced expression of cell surface markers when compared to exposure to antigen in solution. Copland et al teach that expression was highest following exposure to containing tetanus toxoid (TT) stimulated primed T cell proliferation more effectively than TT-neutral liposomes or TT-solution.

It would have been prima facie obvious at the time the invention was made to incorporate measuring autologous T-cell response to tetanus toxin, measuring by said cell's capacity to present quenched FITC-ovalbumin, and said antigen-presenting cell such as immature dendritic cell as taught by Copland et al because Copland et al teach that exposure to FITC–ovalbumin resulted in enhanced expression of cell surface markers when compared to exposure to antigen in solution. Copland et al teach that expression was highest following exposure to containing tetanus toxoid (TT) stimulated primed T cell proliferation more effectively than TT-neutral liposomes or TT-solution.

8. Claims 1-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Thurmond et al WO 2002/21129 in view of Copland et al 2003 (February 14, 2003), Vol.

21 pgs. 883-890 and Wisotzkey et al US Application NO. 20030159168 A1 August 21, 2003.

Claims 1-6 and 9-10 are drawn to a method of identifying a compound capable of modulating the activity of Cathepsin Z in a cell, comprising the steps of: (a) measuring said cell's base level of Cathepsin Z activity in the absence of a candidate compound; (b) introducing said candidate compound; and (c) measuring said cell's level of Cathepsin Z activity in the presence of said candidate compound.

Thurmond et al teach a method of identifying a compound capable of modulating the activity of Cathepsin S in a cell, comprising the steps of: (a) measuring said cell's base level of Cathepsin S activity in the absence of a candidate compound; (b) introducing said candidate compound; and (c) measuring said cell's level of Cathepsin S activity in the presence of said candidate compound.

Copland et al that dendritic cells are highly potent profession antigen-presenting cells essential for initiation of an immune response. Copland et al teach that immature human dendritic cells were generated from peripheral blood monocytes cultured with GM-CSF and IL-4 and that the uptake of antigen by dendritic cells and the degree of expression of the cell surface markers MHC class II, CD80, CD86 and the DC maturation marker CD83, were investigated by incubation solution containing FITC-conjugated antigen. Copland et al teach that exposure to FITC–ovalbumin resulted in enhanced expression of cell surface markers when compared to exposure to antigen in solution. Copland et al teach that expression was highest following exposure to containing tetanus toxoid (TT) stimulated primed T cell proliferation more effectively than TT-neutral liposomes or TT-solution.

Wisotzkey et al teach a method of identifying a compound capable of modulating the activity of Cathepsin Z in a cell, comprising the steps of: (a) measuring said cell's base level of Cathepsin Z activity in the absence of a candidate compound; (b) introducing said candidate compound; and (c) measuring said cell's level of Cathepsin Z activity in the presence of said candidate compound (abstract, [0020],

[0024]), wherein said cell's level of Cathepsin Z activity is measured by measuring antigen presentation (i.e. macrophages see example 19 and example 20). Therefore Wisotzkey et al anticpate a method wherein cell is an antigen-presenting cell. Wisotzkey et al teach a method for treating an autoimmune disease comprising the step of administering the pharmaceutical of a compound capable of modulating the activity of Cathepsin Z, wherein said autoimmune disease is rheumatoid arthritis (see [0015], [0087], [0089], [0172].

It would have been prima facie obvious at the time the invention was made to incorporate a cathepsin Z as taught by Wisotzkey et al and modify the method of identifying a compound capable of modulating the activity of cathepsin as taught by Thurmon et al because both teach a method of identifying a compound capable of modulating the activity of cathepsin. It would also have been prima facie obvious at the time the invention was made to incorporate measuring autologous T-cell response to tetanus toxin, measuring by said cell's capacity to present quenched FITC-ovalbumin, and said antigen-presenting cell such as immature dendritic cell as taught by Copland et al into the method as taught by Thurmond et al because Copland et al teach that exposure to FITC–ovalbumin resulted in enhanced expression of cell surface markers when compared to exposure to antigen in solution. Copland et al teach that expression was highest following exposure to containing tetanus toxoid (TT) stimulated primed T cell proliferation more effectively than TT-neutral liposomes or TT-solution.

Status of the Claims

8. No claims are allowed.

Claims 1-6 and 9-10 are rejected.

Conclusion

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nina A. Archie whose telephone number is 571-272-9938. The examiner can normally be reached on Monday-Friday 8:30-5:00p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Nina A Archie
Examiner
GAU 1645
REM 3B31

MARK NAVARRO
PRIMARY EXAMINER